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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GRUNBERG, ANNE MARIE	
ART UNIT	**PAPER NUMBER**
1661	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,143	KONZAK ET AL.	
	Examiner	Art Unit	
	Anne Marie Grunberg	1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42,44 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/17/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant should proof the specification and claims for any spelling or grammatical errors. For instance, there appears to be a spelling error in claim 26 for "benzaminopurine" which apparently should be changed to --benzylaminopurine--.

Double Patenting

I. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claim 1 and 45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 36 of U.S. Patent No. 6362393. Although the conflicting claims are not identical, they are not patentably distinct from each other because the genus 'wheat' anticipates the species 'plant'.

2. Claims 1 is also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6764854. Although the conflicting claims are not identical, they are not patentably distinct from each other because the genus 'rice' anticipates the species 'plant'.

3. Claim 1 is additionally provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/037,448. Although the conflicting claims are not identical, they are not patentably distinct from each other because the genus 'corn' anticipates the species 'plant'.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4 The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5 Claims 1 and 45, and dependent claims 2-42 and 44, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 45 are indefinite in step (d) due to lack of antecedent basis for "said isolated" microspores. This rejection may be obviated by inserting --purified—in lieu of "isolated".

Claims 1 and 45 are also incomplete because the steps do not result in the product specified by the preamble. The product specified in the preamble is a plant, however the last step in the claims produces a microspore. As a result, it is unclear exactly what Applicant is claiming.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1 and 45, and dependent claims 2-42 and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to wheat microspores, does not reasonably provide enablement for claims broadly drawn to all plant varieties or all plant material. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification only provides guidance for obtaining wheat plants produced from microspores. No guidance is provided regarding the production of any other plants from microspores or from any other plant material not comprising microspores. In contrast, the claims are broadly drawn to any plant variety.

By following the methodologies exemplified in the present specification, one skilled in the art would only have been able to produce wheat from microspores. In Genentech Inc. V. Novo Nordisk A/S (42 USPQ2d 1001), the U.S. Court of Appeals Federal Circuit states on page 1005 that

> "[2] It is true, as Genentech argues, that a specification need not disclose what is well known in the art. *See , e.g. , Hybritech Inc. V. Monoclonal Antibodies, Inc.* , 802 F.2d 1367. 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement...."

It is well known in the art that tissue culture conditions, media, and procedure differ depending on the type of plant, or even genotype due to the unpredictability of tissue culture and regeneration of different plants. Many plant species or genotypes within the species are recalcitrant to regeneration. For example, Kijne states "Many economically important crops are recalcitrant for regeneration." The specification does not teach how any other plant except for wheat can be obtained from the procedure set forth.

Given the claim breadth, unpredictability and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to produce any type of plant from the method as claimed.

This rejection may be obviated by amending the claims so that they are drawn to wheat.

Claim Rejections - 35 USC § 103

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-42 and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genovesi et al in view of Köhler et al.

10. Claims 1-42 and 44-45 are drawn to a method of producing plants from microspores wherein microspores are selected at a developmental stage amenable to androgenic induction. The microspores are subjected to nutrient stress and a sporophytic development inducer, after which they are isolated and cocultured with either ovary-conditioned medium or at least one live

plant ovary. The media may contain an auxin, a cytokinin, or gibberellin. A cell spindle inhibiting agent may be used to induce diploidy. Microspores may also be genetically transformed.

Genovesi et al teach a method of producing plants from purified microspores comprising selecting plant material with microspores at a developmental stage amenable to androgenic induction (column 4, lines 41-48, lines 60-63, for example); subjecting the microspores to temperature stress to obtain stressed microspores (column 4, lines 18-21, for example); contacting the microspores with an amount of a sporophytic development inducer effective to induce sporophytic development (column 16, lines 50-59); and isolating the microspores (column 4, lines 25-27, for example). The microspores within the selected plant material are preferably in the mid uninucleate stage of development (column 4, lines 67-68, for example). Microspores are subjected to temperature stress in a range of temperatures (column 4, lines 20-21; column 5, lines 5-8; page 227, line 4). The sporophytic development inducer is generically described at column 16, lines 49-60. Glycine, described at page 13, line 18 of the specification as a sporophytic development inducer is described at column 16, line 63. Auxins and cytokinin usage is described at column 16, lines 19-47. such as 2,4-dichlorophenoxyacetic acid are widely used in tissue culture (page 219, 3rd paragraph). Genovesi et al teach contacting microspores with an effective amount of a cell spindle inhibiting agent (column 23, line 36, for example) and an effective amount of sporophytic development inducer (column 23, line 32, for instance). Additionally, at column 6, lines 1-40 teach various methods of microspore isolation. Nutrient stress is taught at column 4, lines 18-25, for example. Filtering of the microspores is taught at column 6, lines 1-13, for example.

Genovesi et al do not teach coculturing the isolated microspores with either ovary-conditioned medium or at least one live plant ovary. Genovesi et al also do not teach an aqueous medium comprising NPB 98 nor is the specific duration of nutrient stressing taught.

Köhler et al teach the coculturing of isolated microspores with ovary-conditioned medium (page 181, summary, for example).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to utilize the method of producing plants from microspores as taught by Genovesi et al, and to modify that method by coculturing isolated microspores with ovary-conditioned medium given the advantages of increased regeneration and the guarantee of cell divisions of the isolated microspores as described by Köhler et al in the summary on page 181. The specific medium and duration of nutrient stressing is an optimization of process parameters and are mention by Kohler et al at page 181 and again in the middle of page 182.

11. Claims 1-42 and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasha et al in view of Genovesi et al.

The claims are drawn to a method of producing maize from microspores wherein microspores are selected at a developmental stage amenable to androgenic induction. The microspores are subjected to temperature stress and a sporophytic development inducer, after which they are isolated and cocultured with either ovary-conditioned medium or at least one live plant ovary. Microspores may also be starvation stressed and the media may contain an auxin, a cytokinin, or gibberellin. A cell spindle inhibiting agent may be used to induce diploidy. Microspores may also be genetically transformed.

Kasha et al is a review article summarizing the state of the art of anther and microspore culture in 1990. Kasha et al teach a method of producing plants from microspores comprising selecting plant material with microspores at a developmental stage amenable to androgenic induction (page 224, line 3 under "III. Microspore Culture"); subjecting the microspores to temperature stress to obtain stressed microspores (page 224, halfway through the first paragraph under "III. Microspore Culture"; page 225, bottom of second paragraph; page 227, lines 3-6); contacting the microspores with an amount of a sporophytic development inducer effective to induce sporophytic development (page 227, bottom and middle of the first paragraph); isolating the microspores (page 224, lines 3-8 under "III. Microspore Culture"); and coculturing the isolated microspores with either ovary-conditioned medium or at least one live plant ovary (page 224, first sentence of the second paragraph under "III. Microspore Culture"; page 227, second paragraph). The cultivation medium has an osmolarity between 300 and 500 mOsm (Fig. 1-2, for example). The microspores within the selected plant material are in the mid uninucleate to early binucleate stage of development (page 224, line 13 under "III. Microspore Culture"; page 225, line 8; page 225, first sentence in the second paragraph; page 226, first paragraph under "A. Pollen Embryogenesis"). Microspores can be subjected to temperature stress with either high or low temperatures (page 227, line 4). The sporophytic development inducer includes 2-chloroethylphosphonic acid or other chemical sterilants related to ethylene production (page 227, bottom of first paragraph). Auxins, such as 2,4-dichlorophenoxyacetic acid are widely used in tissue culture as are cytokinins (page 219, 3rd paragraph). Genetic transformation is taught at page 225, first full paragraph. Kasha teaches the use of wheat and barley ovary conditioned medium especially using cultivar Igri (page 224, last paragraph). Kasha et al refer to regeneration in maize (page 213, first paragraph) and recognize that regeneration allows the use of transformation techniques (page 213, first paragraph).

Kasha et al do not teach the specific concentrations of sporophytic development inducer. Kasha et al also do not teach specific auxin concentrations, nor do they teach specific cytokinin or gibberellin concentrations. Kasha et al also do not specifically teach stressed microspores isolated by density centrifugation nor do they teach a solution of mannitol layered over a higher density solution of maltose. Kasha et al also do not teach a Reg-I competency medium, Reg-II shoot regeneration medium, a Reg-III root regeneration medium, IND cultivation medium, MMA incubation medium nor do they teach nutritionally stressing microspores.

Genovesi et al teach mannitol pretreatment (column 3, lines 1-12), sporophytic development inducer (column 7, line 68; column 8, line 17, for example), auxin, cytokinin, and gibberellins (column 2, lines 45-48; column 7, lines 47-68, column 10, lines 46-56; for example; column 14, lines 1-25), and nutritionally stressing microspores (column 9, lines 65-68). Genovesi et al teach a variety of different media (column 2, lines 40-43; column 6, lines 31-40; columns 23-26).

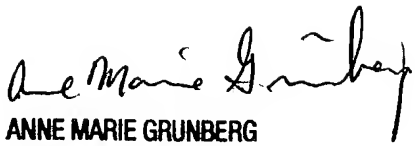
It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to utilize the method of producing plants from microspores as exemplified in the review article by Kasha et al. The state of the art is summarized for the year 1990. It is readily apparent that the various limitations were well known in the art. Particular temperatures for temperature stress applications, as well as time ranges, concentrations of auxins, cytokinins, gibberellins, media type and starvation procedures would have been an optimization of process parameters and would have depended upon the species and genotype. Genovesi et al teach many of these optimizations as discussed above. Density centrifugation was also widely used in the art for separating microspores from other plant materials.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Marie Grunberg whose telephone number is 571-272-0975. The examiner can normally be reached Monday through Friday from 8:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for this group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 571-272-1600.



ANNE MARIE GRUNBERG
PRIMARY EXAMINER